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Proposed Re-evaluation Decision

PRVD2017-09

Isopropyl alcohol

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of isopropyl alcohol, the Health Canada Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of pest control products containing isopropyl alcohol for sale and use in Canada.

An evaluation of available scientific information found that pest control products containing isopropyl alcohol do not present unacceptable risks to human health or the environment when used according to the label directions. No new mitigation measures are proposed for continued registration.

This Proposed Re-evaluation Decision is a consultation document¹ that summarizes the science evaluation for isopropyl alcohol and presents the reasons for the proposed re-evaluation decision. This proposal affects all end-use products containing isopropyl alcohol registered in Canada for use as a surface sanitizer.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of isopropyl alcohol.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What is Isopropyl Alcohol?

Isopropyl alcohol is a hard-surface sanitizer for use in general household cleaning and sanitation, including sanitation of non-food and food contact surfaces such as countertops and to control mould and mildew on pre-cleaned hard non-porous surfaces (non-food use) such as bathroom tiles. The product is applied by spray for one minute of contact time, followed by wiping the surface dry. Currently, one technical grade active ingredient and one domestic class end-use product are registered in Canada.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Isopropyl Alcohol Affect Human Health?

Isopropyl alcohol is unlikely to affect your health when used according to the label directions.

Potential exposure to isopropyl alcohol may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

People could be exposed to isopropyl alcohol through applying the end-use product and by entering treated sites. Exposure to isopropyl alcohol through application and entering treated sites is not of concern.

Occupational exposures of workers (professional cleaners) filling spray bottles and applying the sanitizer using a sprayer, as well as workers re-entering treated sites, are not of concern under current conditions of use. Exposure from residential use of isopropyl alcohol is also not of concern under registered conditions of use. Based upon the use pattern, dietary exposure to isopropyl alcohol is also not of concern.

Environmental Considerations

What Happens When Isopropyl Alcohol is Introduced into the Environment?

Isopropyl alcohol is not expected to be of concern to non-target aquatic and terrestrial organisms. The use pattern for isopropyl alcohol is restricted to indoor uses – little, if any, environmental exposure is anticipated. Therefore, exposure and subsequent potential risk to non-target terrestrial and aquatic organisms is not of concern.

Value considerations

What is the value of isopropyl alcohol?

Isopropyl alcohol has value as a broad spectrum surface sanitizer due to a limited potential for the development of resistance due to rapid evaporation. It also contributes to delaying the development of resistance as an alternative to other sanitizers with different modes of action.

Next Steps

Before making a final re-evaluation decision on isopropyl alcohol, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on isopropyl alcohol. The PMRA will then publish a Re-evaluation Decision² that will include the decision, the reasons for it, a summary of comments received on the proposed decision, and the PMRA's response to these comments.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Isopropyl alcohol is registered for domestic use as a hard-surface sanitizer in general household sanitation such as the cleaning of food and non-food contact surfaces, and to control mould and mildew on pre-cleaned hard non-porous surfaces (non-food use) such as bathroom tiles. It acts by causing membrane damage and rapid denaturation of proteins, with subsequent interference with metabolism and cell lysis. Currently registered products containing isopropyl alcohol are listed in Appendix 1.

2.0 Use Description of Isopropyl alcohol

Isopropyl alcohol is used indoors for general household cleaning and sanitation, sanitation of food and non-food contact surfaces and to control mould and mildew on pre-cleaned hard non-porous surfaces (non-food use) such as bathroom tiles. It is applied as a spray and allowed to remain in contact with surfaces for one minute of contact time. Surfaces are then wiped dry.

3.0 The Technical Grade Active Ingredient and Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common Name	Isopropyl alcohol
Function	Sanitizer
Chemical Family	
Chemical Name	
1 International Union of Pure and Applied Chemistry (IUPAC)	Isopropyl alcohol
2 Chemical Abstracts Service (CAS)	2-propanol
CAS Registry Number	67-63-0
Purity of the Technical Grade Active Ingredient	100%
Registration Number	25081

4.0 Human Health

4.1 Toxicological Summary

Given the incorporation into many drug and healthcare products, the toxicology data requirements were reduced for isopropyl alcohol use in a pest control product. Isopropyl alcohol is of low acute toxicity in the mouse, rabbit, and rat by the oral, dermal, and inhalation routes, respectively. In rabbits, it is considered moderately irritating to the eyes and slightly irritating to the skin.

No short-term or intermediate-term toxicological effects are anticipated from the current use of isopropyl alcohol; therefore, toxicological endpoints for quantitative risk assessment purposes have not been established by the PMRA. No additional toxicology data are required for re-evaluation.

4.2 Occupational Exposure

Because toxicological endpoints were not established by the PMRA due to the low toxicity of isopropyl alcohol, a qualitative worker and residential exposure and risk assessment was completed.

Applicator and loader exposure from re-filling spray bottles is expected to be via both the dermal and inhalation routes. However, this exposure is not expected to be of concern due to the low toxicity of isopropyl alcohol. Furthermore, the exposure from pesticide use of isopropyl alcohol is anticipated to be negligible when compared to the intentional exposure from health care products containing isopropyl alcohol which are applied to the skin and have significantly greater concentrations of the active ingredient (up to 70%) compared to the end use pest control product (3.5%).

Postapplication dermal exposure may be expected by potential contact with residue on disinfected surfaces. However, this exposure is not of concern due to the low toxicity and low concentration of the active in the end-use product. Moreover, a lack of isopropyl alcohol residues is expected on treated surfaces after application as isopropyl alcohol is highly volatile and will rapidly dissipate/evaporate. Furthermore, the label specified use instructions indicate the product is to be wiped off after spraying (food contact surfaces are also to be rinsed after wiping.)

No additional mitigation measures are proposed.

4.3 Dietary Exposure

Isopropyl alcohol is not registered for use on food crops in Canada. Furthermore, due to the low toxicity of isopropyl alcohol, no reference doses for quantitative dietary risk assessments have been established. Exposure to food from contact with treated surfaces is expected to be minimal based on the label-indicated use instructions to wipe and rinse food contact surfaces and the rapid evaporation/dissipation of isopropyl alcohol. Likewise, contamination of drinking water sources is not expected based upon the current use pattern. As a result, potential dietary exposures are not of concern. No additional mitigation measures are proposed.

4.4 Aggregate Exposure

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal, and inhalation). For isopropyl alcohol, aggregate exposure is not of concern due to the low toxicity and low potential dermal, dietary and inhalation exposures to isopropyl alcohol.

4.5 Cumulative Exposure

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that isopropyl alcohol shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

5.0 Environment

The use pattern for isopropyl alcohol as a pest control product is restricted to indoor residential application, and minimal environmental exposure to non-target organisms is expected. As such, a quantitative environmental exposure and risk assessment was not completed for isopropyl alcohol and exposure is not of concern. No additional mitigation measures are proposed.

6.0 Value

Isopropyl alcohol has value as a broad spectrum surface sanitizer due to a limited potential for the development of resistance due to rapid evaporation. It also contributes to delaying the development of resistance as an alternative to other sanitizers with different modes of action.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

Isopropyl alcohol was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and does not meet the Track 1 criteria.

7.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of isopropyl alcohol, contaminants in the technical grade active ingredient were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.³ The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

8.0 Incident Reports

As of 7 June 2017, two human incident reports and one domestic animal incident report involving isopropyl alcohol have been submitted to the PMRA.

One human incident occurred in the US; the subject was hospitalized for two days after accidentally ingesting a product containing multiple active ingredients. The second human incident report included conflicting information about the product used, and no association with isopropyl alcohol could be determined. Similarly, in the domestic animal incident, multiple active ingredients were applied directly to the cat. In all incidents, multiple active ingredients were involved. As such, the role that isopropyl alcohol played in each incident could not be determined.

There were no cases reported to the USEPA's Ecological Incident Information System, as of 5 October 2015.

No risks were identified in this review of isopropyl alcohol incidents.

9.0 Organisation for Economic Co-operation and Development Status of Isopropyl Alcohol

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common problems.

³ *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette*, Part II, Volume 142, Number 13, pages 1611–1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

As part of the re-evaluation of an active ingredient, PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

Isopropyl alcohol is currently acceptable for use in other OECD member countries, including the United States, Australia and Europe. As of 15 February 2017, no decision by an OECD member country to prohibit all uses of isopropyl alcohol for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

PMRA has determined that products containing isopropyl alcohol for sale and use in Canada are acceptable for continued registration. No additional mitigation measures are proposed.

List of Abbreviations

CAS	Chemical Abstracts Service
IUPAC	International Union of Pure and Applied Chemistry
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
TSMP	Toxic Substances Management Policy

Appendix I Registered Isopropyl Alcohol Products as of 9 January 2017.

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
25081	Technical Grade Active Ingredient	S. C. Johnson and Son Ltd.	IPA Technical	Liquid	99.8 %
25089	Domestic		Windex Antibacterial Glass & Surface Cleaner	Solution	Isopropyl alcohol 3.5% Propylene glycol 0.25%

References

Studies/Information Considered in the Value Assessment

B. PUBLISHED INFORMATION

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US EPA. 2012. Aliphatic Alcohols, C1-C5: Human Health Effects Scoping Document for the Registration Review Decision